Dornoch
Medical Systems, Inc

3.0 510(K) SUMMARY OF SAFETY AND EFFECTIVNESS

Sponsor: Dornoch Medical Systems
200 North West Parkway
Riverside, MO 64150

Contact Person: Larry Smith
Product Development Manager
Telephone: (816) 595-4416
Fax: (816) 505-1050

Date: November 25, 2013

Trade Name: Dornoch Ultra Suction Cart and Evac

Product Code / Device: JCX, apparatus, suction, ward use, portable, ac-powered.

Regulation Number / Description: 21 CFR § 878.4780 - Powered suction pump

Device Description:

The Transposal Ultra System (Ultra System) provides a closed, self-contained, reusable cylinder suction system intended to collect and dispose of waste fluids produced through surgical procedures.

The Ultra System is composed of two essential components, the Ultra Suction Cart and the Ultra Evac. The Ultra Cart can be used repeatedly until either 33L (Duo) or 52L (Quad) of fluid has been collected. Once full, the Cart is moved from the OR to the Ultra Evac. The two systems are connected together with the coupler unit on the Ultra Evac. The cleaning / wash cycle is then initiated and the automatic emptying and cleaning occurs.

Intended Use:

The Dornoch Transposal Ultra System is self-powered suction / vacuum pump intended to collect and dispose of liquid waste within Hospital Operating Rooms, Pathology Labs, Surgical Outpatient Centers, and Doctor's Offices.

Comparison to Predicate Device:

The updated Dornoch Ultra Suction cart and Evac (Models DU-2800 QD-2800, DU-500, QD-500 and EV-100) are substantially equivalent to other legally marketed surgical suction systems,

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Specifically the Dornoch Ultra Suction System Models DU-2800 QD-2800, DU-500, QD-500 and EV-100). The systems are identical in design, materials and indications for use.

Performance Data (Nonclinical and/or Clinical):

The Dornoch Suction Carts and Evac have completed the following testing and have been found to be compliant to all applicable clauses of each standard:

IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-1-1: Medical Electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

IEC 60601-1-2: Medical Electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests required for components used as a system.

ISO 10079-1: Medical Suction Equipment Part 1: Electrically powered suction equipment – Safety requirements

Hardware and Software testing, including validation.

Software was proven to be safe and effective when tested to pre-determined acceptance criteria.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 21, 2014

Dornoch Medical System
Larry Smith
Product Development Manager
200 North West Parkway
Riverside, Missouri 64150

Re: K133786
Trade/Device Name: Dornoch Ultra Suction Cart and Evac
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: March 11, 2014
Received: March 12, 2014

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2.0 Indications for Use

Applicant: Dornoch Medical Systems

510(k) Number (if known): K133786

Device Name: Dornoch Ultra Suction System

Indications for Use:

The Dornoch Transposal Ultra System is self-powered suction / vacuum pump intended to collect and dispose of liquid waste within Hospital Operating Rooms, Pathology Labs, Surgical Outpatient Centers, and Doctor's Offices.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off	Ian P. Broverman -S
Division of Surgical Devices	2014.03.20 16:05:22 -04'00'
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